

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of  
LALVANI et al.  
Appln. No. 09/308,725  
Filed: May 24, 1999



Confirmation No. Not Known  
Atty. Ref.: 3772-19  
T.C. / Art Unit: Not Known  
Examiner: Not Known

FOR: ASSAY METHOD FOR PEPTIDE SPECIFIC T-CELLS

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**INFORMATION DISCLOSURE STATEMENT**

June 23, 2005

Hon. Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement (IDS) is intended to be in full compliance with the rules, but should the Examiner find any part of its required content to have been omitted, prompt notice to that effect is earnestly solicited, along with additional time under 37 CFR § 1.97(f), to enable Applicants to comply fully. In particular, if any of the listed documents are missing or incomplete, please contact the undersigned who will provide another copy.

EP 0941478, which is a European counterpart of this application, is the subject of an opposition in the European Patent Office. Oral proceedings are scheduled in the near future and the Examiner is invited to contact the undersigned if he would like to be provided with any of submissions made by the parties. Copies of documents cited in the opposition are attached; they and other documents are listed on the Form PTO-1449.

EP 01109298.8 is a divisional of the aforementioned European counterpart. Search reports for PCT/GB97/03222 and EP 01109298.8, and the Int'l Preliminary Examination Report (IPER) for the parent PCT/GB97/03222 are attached; they are listed on another Form PTO-1449. The documents cited therein were previously listed on a Form PTO-1449 (see the present IDS and that submitted on May 24, 1999).

As provided by 37 CFR §§ 1.97(g) and (h), no representation is being made that a search has been conducted or that this statement encompasses all possible material

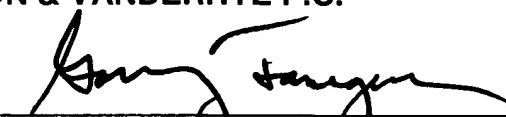
information. Furthermore, no inference should be made that this information or the cited references are prior art merely because they have been submitted for consideration.

Consideration of the foregoing and enclosures, as well as the return of a copy of the Forms PTO-1449 with the Examiner's initials per M.P.E.P. § 609, are earnestly solicited. The Examiner is invited to contact the undersigned if any further information is needed.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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INFORMATION DISCLOSURE  
CITATION

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3772-19

APPLICANT

LALVANI et al.

(Use several sheets if necessary)

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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	FILING DATE		
				CLASS	SUBCLASS	IF APPROPRIATE
AR	5,939,281	08/1999	Lehmann et al.			
BR	6,410,252	06/2002	Lehmann et al.			
CR	2002/0131976	09/2002	Lalvani et al.			
DR	2004/0058399	03/2004	Lalvani			
ER	2004/0131985	07/2004	Lalvani et al.			

## FOREIGN PATENT DOCUMENTS

TRANSLATION

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	YES	NO
FR EP 0296158	06/1992	Europe				
GR WO 95/01441	01/1995	WIPO				

## OTHER DOCUMENTS (including Author, Title, Pertinent pages, Date, etc.)

HR	Andersen et al. "Recall of long-lived immunity to <i>Mycobacterium tuberculosis</i> infection in mice" J. Immunol. 154:3359-3372 (1995)
IR	Billman-Jacobe et al. "Mapping of the T and B cell epitopes of the <i>Mycobacterium bovis</i> protein, MPB70" Immunol. Cell Biol. 68:359-365 (1990)
JR	Brandt et al. "Key epitopes on the ESAT-6 antigen recognized in mice during the recall of protective immunity to <i>Mycobacterium tuberculosis</i> " J. Immunol. 157:3527-3533 (1996)
KR	CSL Biosciences "QuantiFERON-TB™" Direction circular, 19 pages (1994)
LR	De Groote et al. "Novel method for the measurement of cytokine production by a one-stage procedure" J. Immunol. Meth. 163:259-267 (1993)
MR	Di Fabio et al. "Quantitation of human influenza virus-specific cytotoxic T lymphocytes: Correlation of cytotoxicity and increased numbers of IFN-γ producing CD8+ T cells" Int'l Immunol. 6:11-19 (1994)
NR	EIGhazali et al. "Number of interleukin-4- and interferon-γ-secreting human T cells reactive with tetanus toxoid and te mycobacterial antigen PPD or phytohemagglutinin: Distinct response profiles depending on the type of antigen used for activation" Eur. J. Immunol. 23:2740-2745 (1993)
OR	EIGhazali et al. "Comparison of the number of IL-4 and IFN-γ secreting cells in response to the malaria vaccine candidate antigen Pf155/RESA in two groups of naturally primed individuals living in a malaria endemic area in burkina faso" Scand. J. Immunol. 42:39-45 (1995)
PR	Forsberg et al. "The outer surface proteins of Lyme disease borrelia spirochetes stimulate T cells to secrete interferon-gamma (IFN-γ): Diagnostic and pathogenic implications" Clin. Exp. Immunol. 101:453-460 (1995)
QR	Goff "Effect of dexamethasone treatment of tuberculous cattle on results of the gamma-interferon test for <i>Mycobacterium bovis</i> " Immunol. Immunopathol. 53:39-47 (1996)
RR	Hagiwara et al. "Effect of HIV infection on the frequency of cytokine-secreting cells in human peripheral blood" AIDS Res. Hum. Retro. 12:127-133 (1996)
SR	Herr et al. "Detection and quantification of blood-derived CD8+ T lymphocytes secreting tumor necrosis factor α in response to HLA-A2.1-binding melanoma and viral peptide antigens" J. Immunol. Meth. 191:131-142 (1996)
TR	Jones et al. "Removal of false-positive reactions from plasma in an enzyme immunoassay for bovine interferon-γ" J. Immunol. Meth. 155:233-240 (1992)

*Examiner	Date Considered
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Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.



INFORMATION DISCLOSURE CITATION		APPLN. NO.	ATTY. DKT. NO.
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		APPLICANT	
(Use several sheets if necessary)		<u>LALVANI et al.</u>	
		FILING DATE	GROUP
		May 24, 1999	Not Known
<b>OTHER DOCUMENTS (including Author, Title, Pertinent pages, Date, etc.)</b>			
AS	Kabilan et al. "Detection of intracellular expression and secretion of interferon- $\gamma$ at the single-cell level after activation of human T cells with tetanus toxoid <i>in vitro</i> " Eur. J. Immunol. 20:1085-1089 (1990)		
BS	Klinman et al. "ELISPOT assay to detect cytokine-secreting murine and human cells" <i>Current Protocols in Immunology</i> , Coligan et al. (eds.), John Wiley, 6.19.1-6.19.8 (1994)		
CS	Klinman et al. "Activation of interleukin 4- and interleukin 6-secreting cells by HIV-specific synthetic peptides" AIDS Res. Hum. Retro. 11:97-105 (1995)		
DS	Kündig et al. "On the role of antigen in maintaining cytotoxic T-cell memory" Proc. Natl. Acad. Sci. USA 93:9716-9723 (1996)		
ES	Lalvani et al. "Rapid effector function in CD8 $^{+}$ memory T cells" J. Exp. Med. 186:859-865 (1997)		
FS	Lalvani et al. "Human cytolytic and interferon $\gamma$ -secreting CD8 $^{+}$ T lymphocytes" Proc. Natl. Acad. Sci. USA 95:270-275 (1998)		
GS	Mackay "Immunology: Dual personality of memory T cells" Nature 401:659-660 (1999)		
HS	Mehra et al. "Immune response to recombinant mycobacterial proteins in patients with tuberculosis infection and disease" J. Infect. Dis. 174:431-434 (1996)		
IS	Miyahira et al. "Quantification of antigen specific CD8 $^{+}$ T cells using an ELISPOT assay" J. Immunol. Meth. 181:45-54 (1995)		
JS	Oxford Immunotec "New TB test brings tuberculosis care into 21 <sup>st</sup> century" Press release, 3 pages (1994)		
KS	Oxford Immunotec "T SPOT-TB" Instructions for use, 5 pages (1994)		
LR	Oxford Immunotec "Summary of clinical trials completed using T SPOT-TB" 2 pages (1994)		
MS	Pollock et al. "Peptide mapping of bovine T-cell epitopes for the 38 kDa tuberculosis antigen" Scand. J. Immunol. 41:85-93 (1995)		
NS	Rothel et al. "Analysis of polyclonal T-cell determinants on the <i>Mycobacterium bovis</i> secretory protein MPB-70" <i>Vaccines 90</i> , Lome (Program and Abstracts) Abstract E42 (1990)		
OS	Rothel et al. "A sandwich enzyme immunoassay for bovine interferon- $\gamma$ and its use for the detection of tuberculosis in cattle" Austral. Vet. J. 67:134-137 (1990)		
PS	Rothel et al. "The gamma-interferon assay for diagnosis of bovine tuberculosis in cattle: Conditions affecting the production of gamma-interferon in whole blood culture" Austral. Vet. J. 69:1-4 (1992)		
QS	Sørensen et al. "Purification and characterization of a low-molecular-mass T-cell antigen secreted by <i>Mycobacterium tuberculosis</i> " Infect. Immun. 63:1710-1717 (1995)		
RS	Surcel et al. "Th1/Th2 profiles in tuberculosis, based on the proliferation and cytokine response of blood lymphocytes to mycobacterial antigens" Immunol. 81:171-176 (1994)		
SS	Taguchi et al. "Detection of individual mouse splenic T cells producing IFN- $\gamma$ and IL-5 using the enzyme-linked immunospot (ELISPOT) assay" J. Exp. Med. 128:65-73 (1990)		
TS	Whipple et al. "Comparison of the sensitivity of the caudal fold skin test and a commercial $\gamma$ -interferon assay for diagnosis of bovine tuberculosis" Am. J. Vet. Res. 56:415-419 (1995)		
US	Wood et al. "Epitope mapping of the polyclonal bovine T and B cell response to a mycobacterial protein" <i>Frontiers in Mycobacteriology: Immunology of Mycobacterial Infections</i> , Vail, Colorado, Abstract 9 (1990)		
VS	Wood et al. "Development of a simple, rapid <i>in vitro</i> cellular assay for bovine tuberculosis based on the production of $\gamma$ interferon" Res. Vet. Sci. 49:46-49 (1990)		
WS	Wood et al. "Field comparison of the interferon-gamma assay and the intradermal tuberculin test for the diagnosis of bovine tuberculosis" Austral. Vet. J. 68:286-290 (1991)		
XS	Wood et al. "A field evaluation of serological and cellular diagnostic tests for bovine tuberculosis" Vet. Microbiol. 31:71-79 (1992)		
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BT	Aidoo et al. "Identification of conserved antigenic components for a cytotoxic T lymphocyte-inducing vaccine against malaria" Lancet 345:1003-1007 (1995)
CT	Coghlan "Tuberculosis testing finally moves into the 21 <sup>st</sup> century" New Scientist 2390:21 (2003)
DT	Ellefson et al. "Distribution and functional analysis of memory antiviral CD8 T cell responses in HIV-1 and cytomegalovirus infections" Eur. J. Immunol. 32:3756-3764 (2002)
ET	Ewer et al. "Comparison of T-cell-based assay with tuberculin skin test for diagnosis of <i>Mycobacterium tuberculosis</i> infection in a school tuberculosis outbreak" Lancet 361:1168-1173 (2003)
FT	Falk et al. "Identification of naturally processed viral nonapeptides allows their quantification in infected cells and suggests an allele-specific T cell epitope forecast" J. Exp. Med. 174:425-434 (1991)
GT	Falk et al. "Pool sequencing of natural HLA-DR, DQ, and DP ligands reveals detailed peptide motifs, constraints of processing, and general rules" Immunogenetics 39:230-242 (1994)
HT	Hammer et al. "Identification of a motif for HLA-DR1 binding peptides using M13 display libraries" J. Exp. Med. 176:1007-1013 (1992)
IT	Hammer et al. "Promiscuous and allele-specific anchors in HLA-DR-binding peptides" Cell 74:197-203 (1993)
JT	Hammer et al. "Precise prediction of major histocompatibility complex class II-peptide interaction based on peptide side chain scanning" J. Exp. Med. 180:2353-2358 (1994)
KT	Hill et al. "Molecular analysis of the association of HLA-B53 and resistance to severe malaria" Nature 360:434-439 (1992)
LT	Hislop et al. "EBV-specific CD8 T cell memory: Relationships between epitope specificity, cell phenotype, and immediate effector function" J. Immunol. 167:2019-2029 (2001)
MS	Huang et al. "Oxidized LDL induces enhanced antibody formation and MHC class II-dependent IFN- $\gamma$ production in lymphocytes from healthy individuals" Arteriosclerosis, Thrombosis, and Vascular Biology 15:1577-1583 (1995)
NT	Lalvani et al. "An HLA-based approach to the design of a CTL-inducing vaccine against <i>Plasmodium falciparum</i> " Res. Immunol. 145:461-468 (1994)
OT	Lalvani et al. "Potent induction of focused Th1-Type cellular and humoral immune responses by RTS,S/SBAS2, a recombinant <i>Plasmodium falciparum</i> malaria vaccine" J. Infect. Dis. 180:1656-1664 (1999)
PT	Lalvani et al. "Rapid detection of <i>Mycobacterium tuberculosis</i> infection by enumeration of antigen-specific T cells" Am. J. Respir. Crit. Care Med. 163:824-928 (2001)
QT	Link et al. "Acetylcholine receptor-reactive T and B cells in myasthenia gravis and controls" J. Clin. Invest. 87:2191-2196 (1991)
RT	Lu et al. "Interferon $\gamma$ - and interleukin-4-secreting cells in multiple sclerosis" J. Neuroimmunol. 46:129-136 (1993)
ST	Mackay "Immunological memory" Adv. Immunol. 53:217-265 (1993)
TT	McMichael et al. "A new look at T cells" J. Exp. Med. 187:1367-1371 (1998)
UT	Milligan et al. "Analysis of herpes simplex virus-specific T cells in the murine female genital tract following genital infection with herpes simplex virus type 2" Virology 212:481-489 (1995)
VT	Müller et al. "Expansion of gamma interferon-producing CD8 T cells following secondary infection of mice immune to <i>Leishmania major</i> " Infect. Immun. 62:2575-2581 (1994)

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AU	Pamer et al. "Precise prediction of a dominant class I MHC-restricted epitope of <i>Listeria monocytogenes</i> " Nature 353:852-855 (1991)
BU	Pathan et al. "Direct ex vivo analysis of antigen-specific IFN- $\gamma$ -secreting CD4 T cells in <i>Mycobacterium tuberculosis</i> -infected individuals: Associations with clinical disease state and effect of treatment" J. Immunol. 167:5217-5225 (2001)
CU	Rammensee et al. "MHC ligands and peptide motifs: First listing" Immunogenetics 41:178-228 (1995)
DU	Sallusto et al. "Two subsets of memory T lymphocytes with distinct homing potentials and effector functions" Nature 401:708-712 (1999)
EU	Scheibenbogen et al. "CD8 T-cell responses to Wilms tumor gene product WT1 and proteinase 3 in patients with acute myeloid leukemia" Blood 100:2132-2137 (2002)
FU	Wang et al. "Lyme neuroborreliosis: Evidence of persistent up-regulation of <i>Borrelia burgdorferi</i> -reactive cells secreting interferon- $\gamma$ " Scand. J. Immunol. 42:694-700 (1995)
GU	Yi et al. "Idiotype-reactive T-cell subsets and tumor load in monoclonal gammopathies" Blood 86:3043-3049 (1995)
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**U.S. PATENT DOCUMENTS**

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AQ						
BQ						
CQ						
DQ						
EQ						

**FOREIGN PATENT DOCUMENTS**

TRANSLATION

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	YES	NO
FQ						
GQ						

**OTHER DOCUMENTS (including Author, Title, Pertinent pages, Date, etc.)**

HQ	Int'l Search Report for PCT/GB97/03222, 3 pages (1998)
IQ	Int'l Preliminary Examination Report for PCT/GB97/03222, 10 pages (1999)
JQ	European Search Report for divisional EP 01109298.8, 3 pages (2001)
KQ	
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